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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor : Krall et al.
Serial No. : 09/848,121
Filed : May 2, 2001
Title : Defibrillation Electrode Cover
Grp Art Unit : 3762
Examiner : Schaetzle, Kennedy

*I hereby certify that this correspondence is being facsimile
transmitted to the Patent and Trademark Office on July
22, 2004.*

Melanne Williams
Melanne Williams

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

**DECLARATION of JAMES D. LEWIS
UNDER 37 CFR 1.131**

Dear Sir:

1. I, James D. Lewis, have been employed by W.L. Gore and Associates, Inc. (Gore) for over 25 years. During this time I have been engaged in mechanical testing, product development, and business leadership.
2. I hold Bachelor of Science and Master of Science degrees from The Pennsylvania State University in the fields of Engineering Mechanics and Mechanical Engineering, respectively. I also hold of Doctor of Philosophy degree in the field of Biomedical Engineering from Northwestern University.
3. One sample each of covered and uncovered electrode leads was provided to me from the lab book of Robert Krall. The covered lead is labeled as No. 7109104572. Upon information and belief, I understood these samples to be retained samples from an animal study conducted performed outside of Gore. A covering was applied to uncovered samples in order to create covered samples. These samples are from the same source and of the same type used in the study.
4. Measurements of the outer diameters of the covered and uncovered electrode leads were performed under my direct supervision. The measurements were performed using a Unitron profile projector fitted with a Microcode II model 2-M digital readout (Boeckeler Instruments). The diameters of both samples were measured at three sites, i.e., at the ends and in the middle. Two measurements were taken at each site, at orthogonal locations. That is, the diameter of the

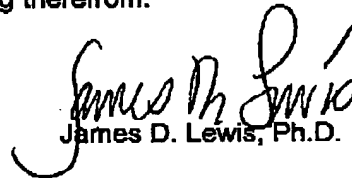
samples was measured then rotated 90 degrees and measured again. Consequently, six diameter measurements were obtained for each sample.

5. The average outer diameter for the covered sample was 1.762 mm. The average outer diameter for the uncovered sample was 1.713 mm. The wall thickness of the cover, which is half the difference of the covered and uncovered electrode outer diameters, was calculated to be 0.024 mm.

The declarant further states that the above statements were made with the knowledge that willful false statements and the like are punishable by fine and/or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that any such willful false statement may jeopardize the validity of this application or any patent resulting therefrom.

Date:

July 21, 2004


James D. Lewis, Ph.D.